DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SuperSonic Imagine
% Ms. Aurelie Gruener
Senior Regulatory Affairs Manager
Les Jardins de la Duranne
510, rue Rene Descartes – Bat. E & F
13 857 Aix-en-Provence
FRANCE

November 20, 2014

Re: K142100
Trade/Device Name: Aixplorer
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 28, 2014
Received: November 5, 2014

Dear Ms. Gruener:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142100

Device Name
AIXPLORER® Ultrasound System

Indications for Use *(Describe)*
The SuperSonic Imagine AIXPLORER® Ultrasound System is indicated for use in the following applications: Abdominal, Small organs, Musculoskelatal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/adult Cephalic.
The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, Intraoperative, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Neonatal/ Adult Cephalic, Fetal/Obstetrics).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use

510(k) number (if known): K142100
Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P, 1, 3, 4, 11	P, 5, 6
	Abdominal (including urolology)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 9
	Intra-operative (Specify) vascular, abdominal, small organs	N		N		N	N 1, 3, 4	N 5, 6, 9
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 9
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic	N		N		N	N 1, 3, 4	N 5, 6
	Trans-rectal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8
	Trans-vaginal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10, 9
	Intravascular							
	GYN	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10
	Pelvic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 10, 9
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SL15-4 transducer (1D Linear Array Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SC6-1 transducer (curved array transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N, 1, 3, 4, 11	N, 5, 6
	Abdominal (including urolology)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intravascular							
	GYN	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Pelvic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SE12-3 transducer (endocavitary transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N, 1, 3, 4, 11	N, 5, 6
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Trans-vaginal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Pelvic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)	P		P		P	P 1, 3, 4	P 5, 6, 8

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SLV16-5 transducer (motorized linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10, 9
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 3, 4	P 5, 6, 8, 10, 9
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SL10-2 transducer (linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9

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Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SMC12-3 transducer (micro-curved transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9
Vessel	Other (Specify)	P		P		P	P, 1, 3, 4	P, 5, 6, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: XP5-1 transducer (Phased Array transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N		N		N	N 1, 3, 4	N 5, 6
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	N		N		N	N 1, 3, 4	N 5, 6
	Neonatal Cephalic							
	Adult Cephalic	N		N		N	N 1, 3, 4	N 5, 6
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N 1, 3, 4	N 5, 6
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
6: Spatial Compounding
7: ShearWave™ Elastography
8: Imaging Guidance for Biopsies
9: Panoramic Imaging
10: 3D Imaging
11: Combined modes include: B+ M modes

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): K142100
Device Name: SLH20-6 transducer (linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify) Vascular, abdominal, small organs	N		N		N	N 1, 3, 4	N 5, 6, 9
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N 1, 3, 4	N 5, 6, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc…)	N		N		N	N 1, 3, 4	N 5, 6, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N 1, 3, 4	N 5, 6, 9
	Musculo-skeletal (Superficial)	N		N		N	N 1, 3, 4	N 5, 6, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N 1, 3, 4	N 5, 6, 9
Vessel	Other (Specify)	N		N		N	N 1, 3, 4	N 5, 6, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging
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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

1) Submitter's name, address, telephone number, contact person

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Chief Executive Officer
Telephone: +33 442 99 24 35

Date: 2014/07/25

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic Ultrasound System with Accessories
Proprietary Name: Aixplorer®

Classification:

Regulatory Class: II

Classification Name:	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Devices

AIXPLORER® Ultrasound Imaging System (K132171), cleared on 09/24/2013
AIXPLORER® Ultrasound Imaging System (K132274), cleared on 09/24/2013
Siemens Acuson S2000TM Diagnostic Ultrasound System (K072786), cleared on 11/13/2007
Philips iU22 Ultrasound System (K093563), cleared on 02/01/2010

4) Description of Device

The SuperSonic Imagine AIXPLORER® system is a cart based ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging studies. The system contains a scan converter and can be coupled to a variety of linear, curved, micro-convex, and motorized linear and phased array transducers to produce images, which are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles. The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode, M-mode, Color Flow, Pulsed Wave Doppler, Harmonic Imaging, Amplitude Doppler, 3D imaging and for ShearWave™ elastography.

5) Intended Use

The SuperSonic Imagine AIXPLORER® ultrasound system and transducer are intended for general purpose pulse echo ultrasound imaging and Doppler fluid flow analysis of the human body.

The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, Intraoperative, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal, Neonata/Adult Cephalic, Fetal/Obstetrics).

6) **Summary of Technological Characterisitics – New Device compared to Predicates**

	Philips iu22 (predicate)	Siemens Acuson S2000™ (predicate)	SuperSonic Imagine AIXPLORER® (predicate K132171)	SuperSonic Imagine AIXPLORER® (predicate K132274)	SuperSonic Imagine AIXPLORER® (new device)
Clinical Applications	---**	General Radiology	---**	---**	---**
	Abdominal,	Identical	Identical	Identical	Identical
	Small Organs*	Identical	Identical	Identical	Identical
	Musculoskeletal	Identical	Identical	Identical	Identical
		Superficial Musculoskeletal	Identical	Identical	Identical
	Fetal	Identical	Identical	---	Identical
	---	Transcranial	---	---	---
	---	OB	Identical	---	Identical
		GYN	Identical	Identical	Identical
	Cardiac	Identical	---	---	---
	---	Pelvic	Identical	Identical	Identical
	Adult and neonatal cephalic	Identical	Identical (for neonatal cephalic)	Identical (for neonatal cephalic)	Identical

	Pediatric	Identical	Identical	Identical	Identical
	Urology	Identical	Identical	Identical	Identical
	---	Vascular	Identical	Identical	Identical
	Peripheral Vascular	Identical	Identical	Identical	Identical
	Ophthalmic	---	---	---	---
	Intra-operative	Identical	---	---	Identical
	Laparoscopic	---	---	---	---
	Trans-rectal	---	Identical	Identical	Identical
	Trans-vaginal	---	Identical	Identical	Identical
	Fetal echo	---	---	---	Identical
Imaging Modes					
Conventional	B-mode,	Identical	Identical	Identical	Identical
	M-mode,	Identical	Identical	---	Identical
	PW,	Identical	Identical	Identical	Identical
	CW (continuous Wave),	Identical	---	---	---
	Color Doppler,	Identical	Identical	Identical	Identical
	Amplitude Doppler	Identical	Identical	Identical	Identical
Other	Harmonic imaging,	Identical	Identical	Identical	Identical
	Spatial Compounding, Panoramic,	Identical	Identical	Identical	Identical
	Contrast	Identical	---	---	---
	---	Identical	Identical	---	---
	---	Elastography	Identical	Identical	Identical
Combination	B-mode+Color,	Identical,	Identical	Identical	Identical
	B-mode+Color+ PW	Identical	Identical	Identical	Identical
	B-mode +PW	Identical	Identical	Identical	Identical
		Identical	---	---	Identical
	---	B-mode+Elastography	Identical	Identical	Identical
Transducers					
Transducer types	Linear Array	Identical	Identical	Identical	Identical
	Curved Array	Identical	Identical	Identical	Identical
	Phased Array	Identical	---	---	Identical
	Laparoscopic	---	---	---	---

	probe Motorized Linear Probe Microconvex probe	Identical Identical	Identical Identical	Identical Identical	Identical Identical
Track	Track 3 (Acoustic Output Display)	Identical	Identical	Identical	Identical
Patient Contact Materials	Yes, per ISO-10993- 1	Identical	Identical	Identical	Identical
Acoustic Output within FDA guidelines	Yes, as per NEMA UD-3	Identical	Identical	Identical	Identical
General Safety	Conforms to IEC 60601-1, IEC 60601-2	Identical	Identical	Identical	Identical

Note:
*: Breast, Thyroid, Testicle, etc
**: --- means not applicable

7) A brief discussion of the non clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Non-clinical testing was conducted per the following standards to support a determination of substantial equivalence to the predicate devices.

Reference Standard	Tests Performed
IEC 60601-1 3rd Edition	All applicable electrical, basic safety and essential performance tests.
UL 60601-1 1st Edition	All applicable electrical, basic safety and essential performance tests specific to the U.S.A.
IEC 60601-1-2 3rd Edition	All applicable testing pertaining to electromagnetic compatibility.
IEC 60601-2-37 2nd Edition	All applicable testing pertaining to the particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
NEMA UD 2 (Rev. 3)	All tests applicable in order to demonstrate compliance with the “Accoustic Output Measurement Standard for Diagnostic Ultrasound Equipment”.
NEMA UD 3 (Rev. 2)	All tests applicable in order to demonstrate compliance with the “Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment”.
ISO 10993-1	Applicable biocompatibility tests per FDA 510(k) Memorandum - #G95-1 – per the appropriate device category.

In addition to the referenced standards testing, performance tests were conducted with respect to new transducers (XP5-1 and SLH20-6).

The above testing confirmed that the Aixplorer System performs according to the stated intended use. All data fell within pre-determined product specifications and external standard requirements. Results of non-clinical testing confirmed the substantial equivalence of the Aixplorer System to the predicate device(s).

8) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Clinical data is not required as the Aixplorer System uses the same technology and principles as predicate devices.

9) Conclusion

The manufacturer and the design and development of the submission device comply with 21 CFR Part 820 and ISO 13485 (2003) Quality Standards. The submission device, designed to comply with applicable safety standards, is tested during manufacturing process to ensure compliance with these standards. Consequently, according tests performed, the opinion of SuperSonic Imagine is the submission device is as safe and effective as the predicate devices cited in item 3.